

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY	)	MDL No. 1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	Civil Action No.
	)	01-CV-12257-PBS
THIS DOCUMENT RELATES TO	)	
	)	Judge Patti B. Saris
<i>State of Montana v. Abbott Labs. Inc., et al.</i>	)	
02-CV-12084-PBS	)	<b>AFFIDAVIT OF</b>
	)	<b>BETTE L. SCHULTZ</b>
<i>State of Nevada v. American Home Prods.</i>	)	
<i>Corp., et al.</i>	)	
D. Nev. Cause No. CV-N-02-0202-ECR	)	
	)	

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STATE OF NEW JERSEY

ss.:

COUNTY OF UNION

BETTE L. SCHULTZ, being duly sworn, deposes and says:

1. I am Vice President for Business Development and Licensing & Mature Products for Novartis Pharmaceuticals Corporation (“NPC”), a defendant in the above-referenced actions. I submit this affidavit in support of NPC’s motions for summary judgment in *State of Montana v. Abbott Laboratories* and *State of Nevada v. American Home Products*. In particular, I explain below that Miacalcin Injection, one of the NPC drugs at issue in these litigations, is a self-administered drug that is rarely administered by a physician and, in any event, it had no competition in any of its therapeutic classes throughout the relevant period of these litigations. I also explain below that two of the drugs at issue – Combipatch and Famvir – were not owned by NPC during parts of the relevant period.

2. I have personal knowledge or have made inquiries with respect to the facts set forth in this affidavit. I would be competent to testify with regard to the facts stated in this affidavit if called upon to do so.

**I. Miacalcin Injection**

**A. Miacalcin Injection is a Self-Administered Drug**

3. I understand that one of the NPC drugs at issue in these litigations is Miacalcin Injection (calcitonin-salmon for injection). The National Drug Code (“NDC”) for Miacalcin Injection is 00078-0149-23. Miacalcin Injection is a “self-administered drug.” This means that it is dispensed by a pharmacist, rather than a physician, and administered by the patient, rather than by a physician.

4. In rare circumstances, Miacalcin Injection is dispensed and administered by a physician. These circumstances include when necessary to demonstrate to a patient how to self-administer the drug, or where a patient is unable to self-administer the drug because he or she is either very ill or incapacitated.

**B. Miacalcin Injection Had No Brand Name Or Generic Competitors Prior To The Filing of Montana And Nevada's Complaints**

5. Miacalcin Injection is indicated for the treatment of: (i) Paget’s Disease, a condition that causes bones to grow larger and weaker than normal; (ii) hypercalcemia, an elevated level of calcium in the blood; and (iii) postmenopausal osteoporosis, a disease associated with a gradual thinning and weakening of the bones, which most frequently occurs in women who have gone through menopause. In practice, physicians primarily prescribe Miacalcin Injection for the treatment of hypercalcemia.

6. Miacalcin Injection was the only drug in injection form in any of its therapeutic classes until January 2006, when Roche Pharmaceuticals began marketing

a drug called Boniva, which also comes in injection form and is indicated for the treatment of postmenopausal osteoporosis.

7. Two other Brand Name drugs are indicated for the treatment of Paget's Disease and postmenopausal osteoporosis, but neither is in injection form or physician-administered. Merck & Co., Inc. markets a drug called Fosamax, which comes in tablet or oral solution form, and The Proctor & Gamble Company and Sanofi-Aventis market a drug called Actonel, which comes in tablet form. As noted above, both of these drugs are self-administered.

8. Because patients prefer to take a tablet or an oral solution rather than to inject themselves with a drug, a physician typically will prescribe Miacalcin Injection for Paget's Disease or postmenopausal osteoporosis only when the patient is medically unable to take Fosamax or Actonel. Therefore, as a practical matter, Miacalcin Injection does not compete with either Fosamax or Actonel, because it is generally only prescribed for patients who cannot tolerate these self-administered alternatives.

9. No generic versions of calcitonin-salmon (the generic name for Miacalcin) exist in injection form.

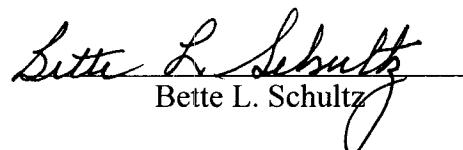
## **II. NPC Did Not Market and Sell CombiPatch Prior to March 30, 2001**

10. I understand that another NPC drug at issue in these litigations is CombiPatch (estradiol/NETA transdermal system), which is a self-administered drug indicated for the treatment of menopausal symptoms. CombiPatch is marketed by Novogyne Pharmaceuticals, a joint venture between NPC and Noven Pharmaceuticals, Inc. The Novogyne joint venture purchased the patent for CombiPatch from Sanofi-Aventis on March 30, 2001. Prior to March 30, 2001, NPC had no role in the marketing

or selling of Combipatch. Accordingly, prior to that date (and, pursuant to regulation, for two years after Sanofi-Aventis sold Combipatch to NPC), Combipatch had National Drug Codes that identified Sanofi-Aventis as the manufacturer.

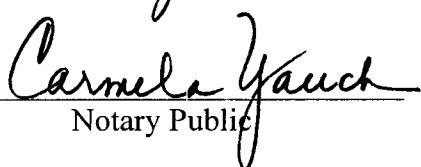
**III. NPC Did Not Market and Sell Famvir Prior to December 31, 2000**

11. I understand that another NPC drug at issue in these litigations is Famvir, which is a self-administered drug indicated for the treatment of recurrent genital herpes and shingles. NPC acquired Famvir from GlaxoSmithKline on December 31, 2000. Prior to December 31, 2000, NPC had no role in the marketing or selling of Famvir. Accordingly, prior to that date (and, pursuant to regulation, for two years after GlaxoSmithKline sold Famvir to NPC), Famvir had National Drug Codes that identified GlaxoSmithKline as the manufacturer.



Bette L. Schultz

Subscribed and sworn to before me  
this 31<sup>st</sup> day of Jan, 2007



Carmela Yauch

Notary Public

**CARMELA YAUCH**  
A NOTARY PUBLIC OF NEW JERSEY  
My Commission Expires Jan. 3, 2009